DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 24, 2014

Custom Orthopaedic Solutions, Incorporated
Justin Baker, Ph.D.
Regulatory and Quality Manager
10000 Cedar Avenue
Cleveland, Ohio 44106

Re: K142072
Trade/Device Name: Glenoid Intelligent Reusable Instrument System (Glenoid Iris)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWS, PHX
Dated: October 21, 2014
Received: October 27, 2014

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142072

Device Name
Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)

Indications for Use *(Describe)*
The Glenoid Intelligent Reusable Instrument System ("Glenoid IRIS") is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Glenoid IRIS is indicated for use in planning and placing the central glenoid guide pin for the DePuy Global AP Shoulder glenoid component, Global Shoulder StepTech Anchor Peg glenoid component, or Delta Xtend Reverse Shoulder metaglene component as an alternative to the standard instruments provided for placing the guide pin with these implant systems.

The indications for use of the DePuy shoulder systems with which the Glenoid IRIS is intended to be used are the same as those described in the labeling for these shoulder systems except that the Glenoid IRIS is not intended for use in hemi-shoulder replacement. The Indications for Use of these DePuy shoulder systems are:

DePuy Global AP Shoulder System and Global StepTech Anchor Peg Glenoid

The DePuy Global AP Shoulder System and Global StepTech Anchor Peg Glenoid are indicated for use in total shoulder replacement surgery for patients suffering from:
• A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
• Fracture-dislocation of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience dictates that alternative methods of treatment are unsatisfactory.
• Other difficult clinical problems where shoulder surgery arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

The Global AP Glenoid and StepTech glenoid components are indicated only for use with bone cement.

DePuy Delta Xtend Reverse Shoulder System

• The Delta Xtend Reverse Shoulder prosthesis is intended for use as total shoulder or hemi-shoulder replacement.
• The Delta Xtend Reverse Shoulder prosthesis is indicated for use in a grossly efficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.
• The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.
• In cases of bone defects in the proximal humerus, the monoblock implant should be used and then only in cases where the residual bone permits firm fixation of this implant.
• Delta Xtend hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively.
• The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. All other components are for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) SPONSOR / MANUFACTURER: Custom Orthopaedic Solutions, Inc.
A subsidiary of Cleveland Clinic
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DATE PREPARED: November 22, 2014

TRADE NAME: Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)

COMMON NAMES: Total shoulder replacement instruments

Product	Product Code	Regulation and Classification Name	Device Class
Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)	**KWS, PHX**	**21 CFR 888.3660 Shoulder, semi-constrained metal / polymer, cemented**	**II**

PREDICATE DEVICES:

Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)(K123122)

DEVICE DESCRIPTION:

The Glenoid Intelligent Reusable Instrument System described in this submission is identical to the Glenoid IRIS cleared in K123122, except for the following modifications:

- In K123122, the IRI legs were plastic, single use, and were shipped sterile in quantities of 2 of each recommended leg length. In this submission, the IRI legs are stainless steel, reusable, and are shipped non-sterile in the Glenoid IRIS instrument

tray/carrier/kit for steam sterilization prior to use at the hospital where the procedure will be taking place. Each Glenoid IRIS kit contains a full set of reusable IRI legs.

- The SmartBone instruments (SmartBone—Pin Trajectory, SmartBone—Reamed, SmartBone—Fixation Feature Prep, and SmartBone—Implant) are made of a different photopolymer from K123122.

-The SmartBone instruments are shipped non-sterile and are sterilized on-site where the procedure will be taking place.

-The IRI wrench was removed from the Glenoid IRIS system and the IRI cap was modified to facilitate tightening and loosening the IRI instrument by hand. The Glenoid IRIS instrument tray was made to include a slot that could be used to replace the disassembly feature of the nubs on the IRI wrench.

-The SmartBone—Pin Trajectory instrument is pre-marked where the recommended IRI legs contact the SmartBone instrument. The marker is a non-toxic marker that is compatible with steam, EO & Sterrad Sterilization. We performed testing to determine how great the risk of the marking from the marker bleeding and or transferring when wiped with a polar and non-polar solvent. The study indicated that the marker was compatible with steam sterilization and did not undergo bleeding. Likewise, the marker did not transfer to a white rag when rubbed with a polar or non-polar solvent.

-The SmartBone mount is made of stainless-steel, is reusable, and is shipped non-sterile as part of the Glenoid IRIS system in a kit/carrier. When the SmartBone is placed on the SmartBone mount, the glenoid is positioned such that vertical is the plane of the scapula. When the SmartBone is set on its base without the SmartBone Mount, the guide pin hole is vertical for ease in setting the IRI.

-The Glenoid IRIS system includes a case/tray carrier for ease in shipping, storing, carrying, and organizing the Glenoid IRI device, the Glenoid IRI legs, the SmartBone instrument (or a place to put the SmartBone instrument, when it arrives after having been shipped separately), and the SmartBone Mount.

-Minor dimensional and aesthetic marking changes to the IRI components

INTENDED USE AND INDICATIONS:

The intended use and indications for use of the modified Glenoid Intelligent Reusable Instrument System remain unchanged from that cleared in K123122.

The **Glenoid Intelligent Reusable Instrument System** ("**Glenoid IRIS**") is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Glenoid IRIS is indicated for use in planning and placing the central glenoid guide pin for the DePuy Anchor Peg Glenoid (APG) component of the DePuy AP Shoulder System, the DePuy Global StepTech Glenoid component, or the DePuy Delta Xtend Reverse Shoulder metaglene component as an alternative to the standard instruments provided for placing the guide pin with these implant systems.

The indications for use of the DePuy shoulder systems with which the Glenoid IRIS is intended to be used are the same as those described in the labeling for these shoulder systems except that the Glenoid IRIS is not intended for use in hemi-shoulder replacement. The Indications for Use of these DePuy shoulder systems are:

DePuy Global AP™ Shoulder System and Global StepTech™ Anchor Peg Glenoid

The DePuy Global AP™ Shoulder System and Global StepTech™ Anchor Peg Glenoid are indicated for use in total shoulder replacement surgery for patients suffering from:

- A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
- Fracture-dislocation of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience dictates that alternative methods of treatment are unsatisfactory.
- Other difficult clinical problems where shoulder surgery arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

The Global AP™ Glenoid and StepTech™ glenoid components are indicated only for use with bone cement.

DePuy Delta Xtend™ Reverse Shoulder System

- The Delta Xtend™ Reverse Shoulder prosthesis is intended for use as total shoulder or hemi-shoulder replacement.
- The Delta Xtend™ Reverse Shoulder prosthesis is indicated for use in a grossly efficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.
- The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

- In cases of bone defects in the proximal humerus, the monoblock implant should be used and then only in cases where the residual bone permits firm fixation of this implant.
- Delta Xtend™ hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively.
- The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. All other components are for cemented use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

BASIS OF SUBSTANTIAL EQUIVALENCE:

The modified **Glenoid Intelligent Reusable Instrument System** ("**Glenoid IRIS**") is substantially equivalent to the Glenoid Intelligent Reusable Instrument System described in K123122 as it is the same system with minor dimensional modifications, modifications to whether the product is reusable and shipped sterile, and modifications to the material from which the instruments are manufactured. The convenience of a system carrier/kit/tray has been included as a part of the Glenoid IRIS system in this submission. The IRI wrench has been removed from the modified system. The modified Glenoid Intelligent Reusable Instrument System functions in the same way as the original Glenoid IRIS. The indications for use for the Glenoid Intelligent Reusable System with these modifications have not changed from K123122.

Non-Clinical Testing
The following testing was performed to demonstrate substantial equivalency of the Glenoid IRIS to the predicate device in K123122.

- Drawings comparison (see list of changes in Device Description above)
- Biocompatibility testing of new photopolymer printed SmartBones
- Shipping/Distribution Testing of new photopolymer printed/packaged SmartBones
- Artificial Cadaver Surgeon Evaluation (Validation)

Clinical Testing
Clinical testing was not necessary to determine substantial equivalence between the modified Glenoid IRIS and the predicate Glenoid IRIS (K123122).

Drawings Comparison
Changes in the IRI drawings were minor and are listed in the Device Description above.

Biocompatibility
As the SmartBone models are considered an external communicating device that contacts

bone/tissue/dentin for a limited duration, cytotoxicity and intracutaneous irritation and sensitization testing was performed. Testing was performed on steam sterilized samples of the SmartBones in the new photopolymer. All tests passed, indicating that the new photopolymer is biocompatible. The original Glenoid IRIS submission likewise used biocompatible materials, and so this modification in the SmartBone material is still substantially equivalent to the original Glenoid IRIS (K123122).

The modified Glenoid IRIS changes the IRI legs from a biocompatible acetal copolymer to a stainless steel that is in conformance with ISO 16061: Instrumentation for use in association with non-active surgical implants – General requirements. In this regard, the change in IRI leg material does not alter the biocompatibility of the modified Glenoid IRIS and the original and modified Glenoid IRIS systems remain substantially equivalent.

Shipping Distribution Testing of New Photopolymer Printed/Packaged SmartBones
The original Glenoid IRIS (K123122) tested packaged SmartBones at temperature extremes of 140°F and -20°F for 48 hours. The modified Glenoid IRIS tested the new SmartBone material with packaged SmartBones in temperature extremes of 140°F and -112°F for 120 hours. The new SmartBone material successfully passed the shipping/distribution temperature tests and drop testing, and in this regard despite the SmartBone material change, remains substantially equivalent to the original Glenoid IRIS submission (K123122).

Artificial Cadaver Surgeon Evaluation
A simulated use, artificial cadaver comparison test between the original and modified Glenoid IRIS was performed. The original Glenoid IRIS was used on an artificial training cadaver of a patient with severe glenoid retroversion five times. The modified Glenoid IRIS was also used on this same patient five times. The mean version and inclination of the original and modified Glenoid IRIS was compared between each other and to the amount of deviation from the planned guide pin location. The modified Glenoid IRIS was shown to be substantially equivalent in performance to the original Glenoid IRIS (K123122).